



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,065	09/13/2005	Heinz Von Der Kammer	37998-237382	5124
26694	7590	03/08/2007	EXAMINER	
VENABLE LLP			CHERNYSHEV, OLGA N	
P.O. BOX 34385			ART UNIT	
WASHINGTON, DC 20043-9998			PAPER NUMBER	
			1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/520,065	Applicant(s) VON DER KAMMER ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 2, in so far as they are drawn to a method of diagnosing a neurodegenerative disease by determining the level of a nucleic acid.

Group II, claim(s) 1, 2, 10 and 20, in so far as they are drawn to a method of diagnosing a neurodegenerative disease by determining the level of a protein.

Group III, claim(s) 3 and 13, in so far as they are drawn to a kit for diagnosing a disease comprising a reagent that detects a nucleic acid.

Group IV, claim(s) 3 and 13, drawn to in so far as they are drawn to a kit for diagnosing a disease comprising a reagent that detects a protein.

Group V, claim(s) 4 and 14, drawn to a modulator.

Group VI, claim(s) 5, drawn to a transgenic animal.

Group VII, claim(s) 6 and 15, in so far as they are drawn to a method for screening for a nucleic acid molecule as a modulator of a disease by contacting a cell with a test compound.

Group VIII, claim(s) 6, 11 and 21, in so far as they are drawn to a method for screening for a protein molecule as a modulator of a disease by contacting a cell with a test compound.

Group IX, claim(s) 7-8 and 16, in so far as they are drawn to a method for screening for a nucleic acid molecule as a modulator of a disease by administering a test compound to an animal.

Group X, claim(s) 7, 8, 16, 22 and 23, in so far as they are drawn to a method for screening for a polypeptide molecule as a modulator of a disease by administering a test compound to an animal

Art Unit: 1649

Group XI, claim(s) 9, 17-19 and 24-25, drawn to an assay.

Group XII, claim(s) 12, drawn to a method of detecting a pathological state of a cell in a sample.

2. The inventions listed as Groups I to XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the methods recited within the first claim were known in the prior art as indicated by the international search report (document WO 2004/005921), therefore, it cannot serve as a unifying special technical feature. The “special technical features” means those technical features that define a contribution over the prior art. (See M.P.E.P. 1850.) Thus, the apparent “special technical feature” of these claims cannot form the basis of unity of invention and the main invention, which forms a single inventive concept is Group I, claims 1 and 2, in so far as they are directed to the first recited product. As such, Groups II to XII directed to independent and distinct products and methods accordingly define a separate invention. Note that 37 C.F.R. § 1.475 (e) states that “The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim”.

Inventions (II and VII to XII) are as being independent and distinct for are directed to different methods and assays that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions. The instant specification does not disclose that these methods and assays would be used together. The inventions of Groups (II and VII to XII) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different

Art Unit: 1649

mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis and screening differ significantly for each of the materials. Inventions of Groups III, IV, V and VI are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has independent utility that is distinct for each invention which cannot be exchanged. Each of these products are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art chemical compounds.

For these reasons the Inventions II to XII are patentably distinct.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.
4. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.
5. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

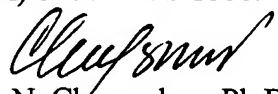
Art Unit: 1649

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

Application/Control Number: 10/520,065

Page 6

Art Unit: 1649

March 5, 2007